In the United States Court of Federal Claims

No. 14-820
(Filed: 15 February 2022[*])

MICHAEL MAGER, as parent of MS. VICTORIA MAGER	*	
Petitioner,	*	Vaccine Act; Off-Table Case; Autoimmune Epilepsy; Actual Causation; Sudden Unexpected Death in Epilepsy ("SUDEP"); Competing Diagnoses; Human Papilloma Virus Vaccine ("HPV").
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
Respondent.	*	

Renee J. Gentry, Vaccine Injury Clinic, George Washington University Law School, of Washington, DC, for petitioner.

Zoe Wade, with whom were *Laurie Wiesner*, Trial Attorney, *Heather L. Pearlman*, Deputy Director, *C. Salvatore D'Alessio*, Acting Director, *Brian M. Boynton*, Acting Assistant Attorney General, Torts Branch, Civil Division, U.S. Department of Justice, of Washington, DC, for respondent.

OPINION AND ORDER

HOLTE, **Judge**.

This case involves the tragic death of a child and the government's system for compensating vaccine-injured children—and by extension, their families. Congress designed the Vaccine Act as part of "the Nation's efforts to protect its children by preventing disease." *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1325 (Fed. Cir. 2011) (quoting H.R. Rep. No. 99-908, at 4 (1986)). "[W]hile most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured." *Id.* "[F]or the relatively few who are injured by vaccines," Congress noted the "opportunities for redress and restitution [were] limited, time-consuming, expensive, and often unanswered." *Id.* In response, "Congress created the Vaccine Program" to "compensate injured persons quickly and fairly" for injuries "either presumed or proven to be causally connected to vaccines." *Id.* This

[*] This opinion was initially filed under seal pursuant to Vaccine Rule 18(b) of the Rules of the Court of Federal Claims. The Court provided the parties 14 days to submit proposed redactions, if any, before the opinion was released for publication. Neither party proposed redactions. This opinion is now reissued for publication in its original form.

Program "exempt[s] petitioners from the burden of proving causation" by removing "the tort requirements of demonstrating that a manufacturer was negligent or that a vaccine was defective." *Id.* In short, the Act "assure[s] parents that when their children are the victims of an appropriate and rational national policy, a compassionate [g]overnment will assist them in their hour of need." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1364 (Fed. Cir. 2019) (Newman, J., dissenting on unrelated grounds) (quoting Sen. Edward Kennedy, S. Comm. on Labor & Human Res.).

Michael Mager seeks compensation for his daughter's seizure disorder and death, which he alleges are the result of her being vaccinated for the human papilloma virus. Ms. Mager's first documented seizure occurred shortly after receiving the first HPV vaccine dose. The seizures subsided for several years until she received a second dose of the HPV vaccine, at which point her seizures returned and became more regular—ultimately resulting in her death. The Special Master denied Mr. Mager's petition because, according to the Special Master, there was insufficient evidence to support a diagnosis of Autoimmune Epilepsy, which the Special Master considered to be necessary for Mr. Mager's argument to succeed. Mr. Mager moves the Court for review of the Special Master's decision denying his petition. According to Mr. Mager, the Special Master abused his discretion by mischaracterizing Mr. Mager's medical theory of his daughter's injury, failing to adhere to precedential case law when considering whether the vaccine caused her injury, and failing to consider the entirety of the evidence. For the following reasons, the Court grants petitioner's motion, vacates the Special Master's order, and remands this case to the Special Master for further proceedings consistent with this opinion.

I. Petitioner's Medical History and the Vaccination

As the basic facts have not changed significantly, the Court's recitation of the background facts draws from the Special Master's Decision Denying Compensation, ECF No. 189. Ms. Mager's health history was relatively normal before receiving the vaccination for the human papilloma virus ("HPV").[1] Ms. Mager received the vaccine on 2 October 2007. Pet. at 1, ECF No. 1. Six weeks later, Ms. Mager suffered a seizure and was taken to a nearby emergency room. Pet'r's Ex. 11 at 28, ECF No. 9-4. The admission notes from that visit state she experienced a seizure followed by a second seizure approximately four minutes later. *Id.* Her head CT scan, urine toxicology screen, and chest x-ray were all normal. *Id.* at 3–4, 13. An electroencephalogram ("EEG") "indicate[d] focal sites of cerebral hyperexcitability which can be associated with partial seizures/epilepsy." *Id.* at 17. Ms. Mager was prescribed Depakote, an anti-seizure medication, and discharged on 15 November 2007. *Id.* at 38.

In a follow-up visit on 12 December 2007, Ms. Mager's physician, Dr. Shafrir, noted that her parents recalled that "for a while [after her initial seizure], [Ms. Mager] was waking up with

[1] While the government argues Ms. Mager's seizures began before she was vaccinated for the human papilloma virus, the parties agree the onset of her seizures is ambiguous and the Special Master made no finding concerning when the seizures began. Mot. for Review Oral Arg. Tr. ("Tr.") at 20:21–22:14, ECF No. 197 ("COURT: Did the Special Master make any findings about seizures occurring before the HPV vaccine? [GOVERNMENT:] He did not. THE COURT: [Petitioner], any follow-up on that? [PETITIONER]: . . . I agree . . . ."). The only exception to Ms. Mager's normal health was, at twelve-years-old, she required speech therapy, demonstrated "poor school performance," "decreased attention" at school, and suffered from enuresis, or bed wetting. Pet'r's Ex. 18 at 5, ECF No. 22-2.

big cuts in her tongue at least twice and also complaining of soreness after waking up and it is possible that these might have been seizures." Pet'r's Ex. 11 at 75. Ms. Mager's stepmother also reported Ms. Mager's enuresis was resolved after she began taking her antiseizure medication, Depakote. *Id.* Dr. Shafrir noted the EEG indicated an impression of "focal onset epilepsy" and "some frontal lobe dysfunction," and he recommended neuropsychological testing. *Id.* at 77.

Approximately two months later, Ms. Mager saw another pediatric neurologist, Dr. Koehn, who ordered another EEG—the results of which were normal. Pet'r's Ex. 6 at 22, ECF No. 8-7. Dr. Koehn noted, referring to the original abnormal EEG, that "[t]he first EEG pattern could represent a fragment/a more lateralized pattern of an underlying generalized discharge or it could in fact be a focal discharge. Therefore, leaving the possibility open for this to have been a primary or secondarily generalized seizure." *Id.* at 20. Although the medication appeared to control her seizure activity, Ms. Mager's father and stepmother noted undesirable side effects of the medication and requested she be weaned off Depakote. *Id.* at 24. Accordingly, Dr. Koehn agreed to gradually wean Ms. Mager from Depakote and referred her for neuropsychological testing. *Id.* at 28; *see also* Pet. at 1.

Shortly after seeing Dr. Koehn, Ms. Mager saw another physician, Dr. Waltonen, for neuropsychological testing. Pet'r's Ex. 6 at 6. Dr. Waltonen observed she had "a history of some type of learning difficulty at least in the speech and language area." *Id.* He also noted Ms. Mager had a family history of epilepsy and seizures on her maternal side. *Id.* at 2. He noted reports of "increasing problems with doing well in school" and Ms. Mager's teachers indicated she had "problems following directions." *Id.* at 1, 4. Ultimately, Dr. Waltonen concluded that "[o]verall, her examination does not reveal evidence of significant cognitive impairment with the exception of these very focal language findings." *Id.* at 6.

From April 2008 to October 2012, Ms. Mager did not experience any seizure activity and appeared to function normally. Her school records did not indicate any abnormalities. *See* Pet'r's Ex. 83, ECF No. 144-3. The results of sport physicals she received in August 2009 and March 2012 were normal. Pet'r's Ex. 10 at 15–17, ECF No. 9-3; Pet'r's Ex. 14 at 1–2, ECF No. 12-2. During a physical exam in January 2012, she reported she had not experienced seizure activity for four years. Pet'r's Ex. 10 at 18. Ms. Mager received her second HPV vaccination on 11 September 2012. Pet'r's Ex. 4 at 1, ECF No. 8-5. The following month, on 10 October 2012, she suffered a seizure and was taken to the emergency department of a nearby medical center. Pet'r's Ex. 7 at 9, ECF No. 8-8. Her evaluation, which included an EKG, was normal. *Id.* at 13–14. She was diagnosed with a "[p]robable seizure" and discharged. *Id.* at 14.

In a visit with her primary care doctor the next month, she reported two additional seizures occurring on 19 October 2012 and 7 November 2012 after her ER visit. Pet'r's Ex. 9 at 39, ECF No. 9-2. Her doctor prescribed an antiseizure medication, Depakote, and referred her to a neurologist. *Id.*

Neurologist Dr. Edgar saw Ms. Mager a couple months later in January 2013. Pet'r's Ex. 9 at 24–25. According to Dr. Edgar's note, "[t]he EEG is normal during wakefulness. During sleep there is activation of infrequent potentially epileptiform activity over the left frontal and

bioccipital head regions, consistent with the patient's history of generalized seizures." *Id.* at 25. Dr. Edgar believed Ms. Mager suffered from primary generalized seizure disorder, and he noted the "age of onset at approximately 11 years of age suggests the possibility of juvenile myoclonic epilepsy, although no myoclonic seizures are reported." *Id.* at 31. He recommended Depakote, but due to Ms. Mager's objections, he directed her to begin weaning off Depakote and prescribed Keppra, an alternative antiseizure medication, instead. *Id.* at 8.

Dr. Edgar observed during a follow-up appointment in July 2013 that Ms. Mager's compliance with her Keppra prescription was "less than ideal"; she had a sub-therapeutic level of the medication in her blood according to a test on 30 May 2013. Pet'r's Ex. 9 at 3. Ms. Mager wanted to stop using Keppra, but Dr. Edgar persuaded her to remain on the drug given her history of seizures. *Id.* at 4. Due to her age at the onset of her seizure condition, Dr. Edgar again noted "probable juvenile myoclonic epilepsy." *Id.*

Months later, on 11 January 2014, Ms. Mager was found unresponsive at a friend's house and was rushed to the emergency department of a nearby hospital where she was pronounced dead upon arrival. Pet'r's Ex. 8 at 2, ECF No. 8-9. The local police department reported a witness statement that Ms. Mager had been "missing a lot of doses of her medication," and her father reported that "she was having seizures more frequently." Pet'r's Ex. 13 at 2, ECF No. 9-6.

According to an autopsy, Ms. Mager suffered pulmonary edema and brain changes consistent with a seizure disorder. Pet'r's Ex. 16 at 10, ECF No. 18-2. There was subpial gliosis in sections of her brain. *Id.* at 16. A toxicology screen showed therapeutic levels of Keppra in her blood. Pet'r's Ex. 13 at 11. The cause of Ms. Mager's death was "seizure disorder" according to her death certificate. Pet'r's Ex. 1 at 1, ECF No. 8-2.

The parties agree Ms. Mager suffered from a seizure disorder that caused her death, Tr. 6:14–16, but they dispute the underlying diagnosis. Pet'r's Prehr'g Br. at 9, ECF No. 168 ("Petitioner contends [Ms. Mager] suffered from autoimmune epilepsy that resulted in sudden unexpected death with epilepsy or SUDEP."); Gov't's Prehr'g Br. at 1, ECF No. 180 ("the evidence supports that Ms. Mager most likely suffered from juvenile myoclonic epilepsy").

II. The Petition and Procedural History Before the Special Master

Petitioner filed his petition alleging the HPV vaccination caused Ms. Mager to suffer a seizure disorder leading to her death on 11 January 2014. Pet. at 2. All relevant medical records were submitted, and the record was complete on 17 February 2015. *See* Statement of Completion, ECF No. 23. A couple months later, the Secretary filed his report contesting causation and arguing Ms. Mager's seizure disorder preexisted her vaccination. *See* Resp't's Rule 4(c) Report, ECF No. 25. After a change in counsel and experts, and multiple extensions of time, the parties submitted their experts' reports. *See* Pet'r's Ex. 55, ECF 116-1; Gov't's Ex. Z, ECF No. 128-1; Gov't's Ex. AA, ECF No. 129-1; Pet'r's Ex. 85, ECF No. 165-2; Gov't's Ex. CC, ECF No. 182-1; Gov't's Ex. BB, ECF No. 183-1. Petitioner's expert, Dr. Shafrir, asserted Ms. Mager's epilepsy was autoimmune in nature based, in part, on autoimmune reactions to the vaccine. Pet'r's Ex. 55 at 18. Respondent's experts, Dr. Kohrman and

Dr. Fujinami, however, both stated Ms. Mager suffered from juvenile myoclonic epilepsy ("JME"). Gov't's Ex. Y at 7, ECF No. 95-3; Gov't's Ex. CC at 1–2.

The Special Master ordered the parties to submit briefs in advance of potential adjudication on 20 November 2019, ECF No. 142. After multiple extensions, Mr. Mager filed a supplemental expert report from Dr. Shafrir on 25 July 2020, ECF No. 167, and his brief on 27 July 2020, ECF No. 168. The Secretary, again after multiple extensions, filed his supplemental expert reports from Dr. Fujinami and Dr. Kohrman, as well as his brief, on 10 February 2021, ECF Nos. 180–83. Mr. Mager filed his reply brief on 26 March 2021, ECF No. 186.

In the interim period between the parties' briefing and the Special Master's decision, a significant colloquy between the Special Master and petitioner took place. The Special Master issued an order in June asking petitioner to "identify the source of the diagnostic criteria for autoimmune epilepsy listed in his [prehearing] brief." Order at 1, ECF No. 187. Petitioner responded accordingly the next day but noted "[t]he criteria are discussed in that section *solely* to demonstrate that autoimmune epilepsy can present as milder epilepsy." Status Report Re Order of June 16, 2021 ("Pl.'s Resp. to Special Master's 16 June 2021 Questions") at 1, ECF No. 188 (emphasis added).

The Special Master then issued his decision denying compensation the following month on 29 July 2021. *See* Decision Den. Compensation, ECF No. 189. In his decision, the Special Master denied petitioner's claim on the basis that there was insufficient evidence to support a diagnosis of Autoimmune Epilepsy. *Id.* at 16–17.

A. Expert Reports

In weighing the evidentiary value of the parties' experts' opinions, the Special Master determined petitioner's expert, Dr. Shafrir, and the government's expert, Dr. Kohrman, both "have ample experience and expertise in pediatric neurology[;] Dr. Kohrman has a notable special expertise in epilepsy." Decision Den. Compensation at 9. The Special Master noted "Dr. Shafrir's certifications and topics of focus in his publications are certainly relevant and helpful to this case," but determined "Dr. Kohrman's specialty in epilepsy—particularly his board certification with a subspecialty in epilepsy and focus on pediatric epilepsy—makes him particularly qualified to opine on a case in which potential diagnoses of autoimmune epilepsy or juvenile myoclonic epilepsy are at play." *Id.*

Dr. Shafrir, believes Ms. Mager's seizures and death were caused by a neurological reaction to the HPV vaccination. He explains:

> [B]ecause of some unknown and a very rare genetic susceptibility, [Ms. Mager] had an abnormal immune reaction to the HPV vaccination which produced brain inflammation in autoimmune epilepsy. The reactivation of the autoimmune and inflammatory mechanism with the second vaccination, produced recurrence of her epilepsy with more frequent seizures. The mechanism is likely based on molecular mimicry which could be supplemented by activation of the innate immune system . . . .

Pet'r's Ex. 55 at 17. The HPV vaccine, according to Dr. Shafrir, is a uniquely potent stimulator of the immune system. *Id.* at 19 ("In contrast to many other vaccines, the level of antibodies produced by [sic] HPV vaccine is more than 10 to 100[-]fold higher than the level of antibodies produced by the natural infection."). The medical literature he cites identifies examples of brain autoimmunity related to the HPV vaccination and proteins. *Id.* "[A]wareness of autoimmune epilepsy has dramatically increased in the last several years," says Dr. Shafrir, to the extent that "[c]hecking autoantibodies in appropriate cases of intractable epilepsy has become the standard of care." *Id.* at 18–19.

Here, there is strong evidence of an autoimmune inflammatory reaction, according to Dr. Shafrir, because Ms. Mager's autopsy report found evidence of gliosis which suggests inflammation of the brain. *Id.* at 20. He further reasons the occurrence and recurrence of Ms. Mager's seizures in correlation with the HPV vaccine demonstrates it caused her seizures and death. He explains:

> The relationship between vaccinations and her seizures is based on a "rechallenge" test and has been performed here with another episode of seizure occurring after her second HPV vaccination but not after [other vaccinations] given before the second HPV vaccination. One has to understand that in clinical situations, such a rechallenge for any treatment, medication or immunization would suffice to confirm a causal relationship.

Pet'r's Ex. 55 at 17, ECF No. 116-1. Dr. Shafrir emphasized the importance of the relationship between the vaccination and Ms. Mager's seizures in a supplemental report:

> [T]he near identical sequence of events following each of the HPV vaccinations qualify as "certain" in the causality assessment of suspected adverse drug reactions, according to the existing criteria described in [the cited medical literature] in my first report. What is crucial here is the fact that Ms. Mager could stop antiepileptic medication and remained seizure free throughout the entire period of more than three years before the second vaccination. After the second vaccination in the recurrence of the seizures, the seizures became more frequent. In part, this is a result of her lack of easy access to neurological care, insurance issues which may have affected her ability to get her medications, and general lack of compliance. According to a witness after her death, she reported that she has seizures every week. This suggests that the immune reaction to the HPV vaccine, which produced the seizures, was more severe and more prolonged after the second vaccination probably because of the presence of immunological memory.

Pet'r's Ex. 85 at 1 (citations omitted). This relationship between the vaccination and the seizures, Dr. Shafrir reasoned, "is another strong support . . . for the causal relationship between the [HPV] vaccination and [Ms. Mager's] seizure disorder and unexpected death." Pet'r's Ex. 55 at 20.

The government submitted reports from two experts, Dr. Kohrman and Dr. Fujinami, both of whom dispute Dr. Shafrir's theory of autoimmune epilepsy caused by the HPV vaccine. *See* Gov't's Exs. Z, AA, BB, CC. According to Dr. Kohrman, evidence weighing against a diagnosis of autoimmune epilepsy includes: (1) treating physicians diagnosed Ms. Mager with primary generalized epilepsy; (2) evidence Ms. Mager's seizures predated the HPV vaccine; (3) absence of history of focal clinical seizures in the medical record; (4) absence of evidence indicating an autoimmune process in the autopsy report; and (5) absence of test results indicating presence of antineuronal antibodies. Gov't's Ex. BB at 12.

Regarding Dr. Shafrir's emphasis on the correlation between the HPV vaccine and Ms. Mager's seizures, Dr. Kohrman commented:

> Given the diagnosis of a primary generalized epilepsy, that was never adequately treated [due] to family request and behavior, and the lack of patient taking [sic] meds[,] [h]er history and clinical course cannot be considered a challenge[-]rechallenge. It was never documented medically that she was seizure[-]free prior to [sic] second vaccination. The[re] is not [sic] contemporaneous medical record of her seizures noted between July 2008 and her second vaccination. Her seizures were primarily nocturnal and she did not always recognize these according to her [f]ather.

Id. (citation omitted). Ms. Mager's diagnosis, according to Dr. Kohrman, was most likely juvenile myoclonic epilepsy ("JME"). *Id.* at 14. Dr. Kohrman explains:

> JME is an idiopathic generalized epilepsy syndrome characterized by myoclonic seizures, generalized tonic-clonic seizures, and absence seizures. It is extremely common, accounting for [twenty-six percent] of idiopathic generalized epilepsies . . . and [ten percent] of all epilepsies . . . . [T]he average age of onset is 15.1 years ([seven to twenty-eight] years) with a slight female predominance. In the classic syndrome of JME, myoclonic seizures may precede the first generalized tonic-clonic seizure . . . by [six to twelve] months, although [generalized tonic-clonic seizures] occur as the first seizure type in approximately one-third of patients. Some have proposed specific subgroups of JME separating those patients who present with typical childhood absence or juvenile absence seizures, although this is much less common than the classical presentation of JME, accounting for only [ten percent] of cases . . . . Photosensitivity is relatively common, occurring in approximately [thirty percent] of patients.

Id. at 2. Dr. Kohrman reviewed Ms. Mager's medical history and determined her diagnosis was most likely JME. *Id.* at 15. He pointed to her treating physician's comment that her epilepsy was likely JME due to her age. *Id.* at 2, 14 (citing Pet'r's Ex. 10 at 23). He believed her medical history also supported a diagnosis of JME; specifically, that her seizures appeared to be controlled with antiseizure medication and other evidence such as her history of tongue-biting and enuresis (which he considered to be evidence of nocturnal seizures), her family history of epilepsy, and her history of speech and learning problems. Gov't's Ex. BB at 2, 14. He also explained her seizures were described as generalized tonic-clonic seizures and her EEGs showed

generalized epileptiform activity, both of which are consistent with a diagnosis of JME. *Id.* at 14.

Dr. Kohrman did not believe Ms. Mager suffered from autoimmune epilepsy. *Id.* at 12. He repeated her treating physician's diagnosis of primary generalized epilepsy and noted JME falls on a spectrum of primary or idiopathic generalized epilepsies. *Id.* at 2, 12. He also believed her seizure disorder predated her HPV vaccination and observed there was an absence of evidence of antineuronal antibodies. *Id.* at 12. Regarding Dr. Shafrir's suggestion that the autopsy revealed gliosis which indicated inflammation in the brain, Dr. Kohrman explained "subpial gliosis is a regular finding in juvenile myoclonic epilepsy. The pathologist at necropsy concluded this was a typical finding in epilepsy and [Ms. Mager had] generalized epilepsy . . . ." *Id.* at 15. Dr. Fujinami also believed Ms. Mager suffered from JME and observed that Ms. Mager's seizures were not resistant to antiseizure medication, as would be the case if her seizures were caused by autoimmune epilepsy. Gov't's Ex. CC at 1.

B. The Special Master's Decision Denying Compensation

The Special Master's analysis in terms of the diagnostic criteria for autoimmune epilepsy is clear, thorough, and well-reasoned. The Special Master began his analysis by weighing the relative qualifications of the experts, specifically Dr. Shafrir and Dr. Kohrman. Decision Den. Compensation at 9. The Special Master considered both experts to be well qualified but found "Dr. Kohrman's specialty in epilepsy—particularly his board certification with a subspecialty in epilepsy and focus on pediatric epilepsy—makes him particularly qualified to opine on a case in which potential diagnoses of autoimmune epilepsy or juvenile myoclonic epilepsy are at play." *Id.*

Next, the Special Master carried out a thorough analysis applying the diagnostic criteria petitioner identified for autoimmune epilepsy to the facts of this case. He explained this was necessary "because [petitioner's] theory of causation relies on an autoimmune disease causing neuroinflammation."[2] *Id.* at 4. The three diagnostic criteria the Special Master considered were: "(1) 'demonstration of autoantibodies against neuronal components in the patient's blood'; (2) in most patients, seizures that 'may not respond to regular antiepileptic medications but respond to immunomodulatory treatment'; and (3) 'occurring in relation to an autoimmune disease or autoimmune encephalitis.'" *Id.* at 10 (citing Pet'r's Prehr'g Br. at 9–10, ECF No. 168).

Looking at the first criterion, the presence of autoantibodies against neuronal components in the patient's blood, the Special Master found there was "no affirmative evidence on this point." *Id.* at 10. This is a key criterion because the presence of neuronal antibodies in the blood is conclusive evidence of an autoimmune reaction. *Id.* Unfortunately, an antibody test was not performed in this case. Decision Den. Compensation at 10. The Special Master noted

[2] Petitioner admits Ms. Mager's condition does not fit the diagnostic criteria for autoimmune epilepsy. Tr. at 34:7–20. When asked why petitioner included the diagnostic criteria for autoimmune epilepsy, counsel for petitioner explained: "I do not believe that she meets the diagnostic criteria. Neither does Dr. Shafrir, and he stated that for the most severe case. . . . [O]ften in clinical settings, you're going to get a diagnosis that doesn't . . . meet all the diagnostic criteria. We've not alleged that she meets that diagnostic criteria in this case. We are alleging . . . that she meets the general clinical definitions based on the etiology of her epilepsy." Tr. at 34:11–20.

petitioner's "potentially valid reasons" why Ms. Mager's treating physicians may not have thought to perform tests for autoimmune antibodies—particularly that "autoimmune epilepsy is a relatively 'emerging field.'" *Id.* (citing Pet'r's Reply to Resp't's Prehr'g Mem. at 18, ECF No. 186). The Special Master reasoned, however, "a *lack* of evidence on this point does not help Mr. Mager's case." *Id.* "While this fact is not dispositive as to the determination of whether [Ms. Mager] had autoimmune epilepsy, and does not rule out autoimmune epilepsy," the Special Master reasoned, "a lack of testing also does not provide any affirmative evidence supporting an autoimmune epilepsy diagnosis." *Id.*

The Special Master considered the autopsy report's finding of gliosis and whether it was an indicator of an inflammatory process, as Dr. Shafrir argued, but concluded the evidence was tenuous because the experts dispute its significance as it pertains to evidence of autoimmunity. *Id.* at 11. The Special Master cited Dr. Fujinami, who argued gliosis is a "common finding in epilepsy and represents the result of a neuronal injury and cell death . . . and not an acute or chronic inflammatory process related to vaccination," and Dr. Kohrman who said gliosis is a "regular finding in juvenile myoclonic epilepsy." *Id.* at 10–11 (citing Gov't's Ex. Y at 7; Gov't's Ex. BB at 15). Besides, the Special Master reasoned, "[i]t also does not provide evidence of autoimmune antibodies in [Ms. Mager's] blood, which is the actual relevant criterion in terms of testing for a diagnosis of autoimmune epilepsy." Decision Den. Compensation at 11. Thus, the Special Master concluded there was an absence of evidence indicating the presence of autoantibodies, the first criterion for a diagnosis of autoimmune epilepsy. *Id.* at 10.

Regarding the second criterion, the Special Master found there was insufficient evidence to conclude Ms. Mager's seizures were resistant to antiseizure medication. *Id.* at 12. The Special Master considered petitioner's argument that at least two incidents demonstrated Ms. Mager's seizures were refractory: (1) Ms. Mager suffered a seizure the night she was discharged from the hospital in November 2007 after she started taking Depakote, an antiseizure medication; and (2) Ms. Mager had a therapeutic level of antiseizure medication, Keppra, in her blood at the time of her death. *Id.* at 11. The Special Master was not persuaded either incident was the result of resistance to antiseizure medication. *Id.* at 12. In the first instance, the Special Master reasoned, Ms. Mager's seizures and seizure-related activity (e.g., enuresis) appeared to be controlled while she continued taking Depakote. *Id.* at 11–12. In the second, multiple sources of evidence suggested Ms. Mager did not take her medication as prescribed in the period preceding her death. Decision Den. Compensation at 12. In sum, the Special Master found the evidence in favor of finding the petitioner satisfied the second criterion was unpersuasive.

Turning to the third criterion, the Special Master carried out an extensive analysis as to whether Ms. Mager suffered from autoimmune encephalitis.[3] *Id.* at 13. The Special Master evaluated six clinical features of autoimmune encephalitis the petitioner identified. *Id.* (citing Pet'r's Reply to Resp't's Prehr'g Mem. at 11). Those six clinical features include:

[3] At oral argument, petitioner argued: "[W]e never alleged autoimmune encephalitis. We were, again, submitting evidence showing that anything that can cause this severe a storm of autoimmune encephalitis can cause something less than that." Tr. at 29:22–30:1. In petitioner's prehearing reply brief, however, "[p]etitioner contends [Ms. Mager] suffered from autoimmune-triggered encephalitis, which caused her epilepsy and eventual SUDEP." Pet'r's Reply to Resp't's Prehr'g Mem. at 10.

> (1) Focal seizures, particularly focal motor and focal dyscognitive, secondary generalized seizures; (2) seizure clusters, status epilepticus; (3) seizures and epilepsy of unknown cause; (4) refractory seizures; (5) associated features of encephalopathy, movement disorders, neuropsychiatric symptoms, cognitive or memory impairment; and (6) history of autoimmune diseases (personal or family).

Id. The Special Master found there was insufficient evidence to satisfy these criteria, except the third (i.e., seizures of unknown cause). *Id.* at 15–16. The Special Master summed up:

> [T]he only diagnostic criterion that Mr. Mager has met his burden to show is that [Ms. Mager's] seizures were of an unknown cause. It follows that Mr. Mager has then not met his burden in showing that [Ms. Mager] suffered from autoimmune encephalitis, as this is only one of six diagnostic criteria, and one that is relatively less weighty given that it by definition indicates a *lack* of information regarding [Ms. Mager's] condition.

Id.

III. Petitioner's Motion for Review and Respondent's Arguments

A. Petitioner's Arguments

Petitioner alleges "[t]he Special Master abused his discretion by mischaracterizing [p]etitioner's position with respect to diagnosis and ignoring significant points made by [p]etitioner's expert with respect to the diagnosis and causation, to such an extent as to deny [p]etitioner his full and fair hearing." Mot. for Review at 2, ECF No. 191. According to petitioner, the Special Master commits two errors regarding Ms. Mager's diagnosis: (1) he conflates her diagnosis before death with her alleged injury; and (2) he focuses on the autoimmune epilepsy portion of Dr. Shafrir's proposed causation theory and fails to consider Dr. Shafrir's theory in its full context. *Id.* at 16. Petitioner argues he "is not hinging his case on a diagnosis of autoimmune epilepsy, *nor* did he proffer the diagnostic criteria to support a diagnosis of autoimmune epilepsy. Rather, [p]etitioner argue[s] that [Ms. Mager] experienced [sudden unexpected death with epilepsy] as a result of her epilepsy which was, yes, likely to be autoimmune in nature." *Id.* at 17.

Petitioner maintains his "predominant argument was that [Ms. Mager] experienced challenge/rechallenge . . . . Rechallenge is *not* dependent on a finding that [Ms. Mager] suffered from autoimmune epilepsy. It is dependent on [Ms. Mager] suffering an adverse event, in this case seizures, after more than one administration of a particular vaccine, e.g.[,] the HPV vaccination." *Id.* While petitioner's expert, Dr. Shafrir, testified Ms. Mager's HPV vaccination triggered autoimmune epilepsy in Ms. Mager, petitioner argues "the complexity of her diagnosis cannot be stripped down to the three [diagnostic] criteria [for autoimmune epilepsy] as the Special Master did in this case. *Particularly*, when [those] criteria [are] offered to demonstrate that autoimmune epilepsy can present in a range of severity including the milder epilepsy from which [Ms. Mager] suffered." *Id.*

Petitioner argues the Special Master improperly failed to consider the entirety of petitioner's claim by limiting his analysis to the diagnostic criteria for autoimmune epilepsy before dismissing the case. *Id.* at 18. According to petitioner, the Special Master's reliance on *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343 (Fed. Cir. 2011), and *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339 (Fed. Cir. 2010), is misplaced, and the Special Master should have analyzed the case under *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 (Fed. Cir. 2005), and its progeny because *Lombardi* and *Broekelschen* are distinguishable. Mot. for Review at 18.

Plaintiff further argues the Special Master was obliged to consider the *entire* record before disposing of the case due to his decision to not hold a hearing. *Id.* at 15. To support his proposition that the procedural posture of a case affects the Special Master's burden to consider the evidence, petitioner cites *Moriarty by Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1333 (Fed. Cir. 2016). *Id.* "In the instant matter," petitioner argues, "the Special Master's refusal to conduct an evidentiary hearing . . . renders it particularly important that he review the *entire* record . . . . If a Special Master may not, as a matter of law, decline to consider evidence on the record only because it was not discussed at hearing [as was the case in *Moriarty*], it is even more imperative that he consider all the evidence when he also declines to *conduct* a hearing." *Id.*

B. Respondent's Arguments

Respondent argues petitioner affirmatively articulated a causation theory that hinges on an autoimmune epilepsy diagnosis. Resp. to Mot. for Review at 10, ECF No. 193. Specifically, respondent points to petitioner's statements that his theory of causation is a "neurological autoimmune process triggered by the HPV vaccine, causing autoimmune epilepsy[,]" and "the initial HPV vaccine dose caused [Ms. Mager's] epilepsy and the subsequent dose aggravated that condition through a neurological autoimmune process causing autoimmune epilepsy." *Id.* (quoting Pet'r's Prehr'g Br. 16, ECF No. 168). Respondent maintains "[i]t is thus plain that petitioner's case hinged on the argument that Ms. Mager developed autoimmune epilepsy." *Id.*

Respondent cites the Special Master's decision which summarizes the experts' opinion on Ms. Mager's diagnosis:

> Dr. Shafrir asserted a diagnosis of autoimmune epilepsy based, in part, on what he deemed neurological reactions to the vaccine that suggested underlying autoimmune encephalitis. Dr. Kohrman, however, maintained a diagnosis of juvenile myoclonic epilepsy ("JME"), based on his view that [Ms. Mager] suffered pre-vaccination seizure activity, non-focal (i.e. generalized) seizures, and a lack of evidence regarding an autoimmune process in [Ms. Mager's] autopsy. Dr. Fujinami agreed with the JME diagnosis, highlighting that [Ms. Mager's] seizures were not treatment resistant, as would be true of seizure activity involved in autoimmune epilepsy.

Id. at 11 (quoting Decision Den. Compensation at 3). Respondent further cites the Special Master's conclusion that "[t]he difference between autoimmune epilepsy and JME . . . affects the

outcome of [petitioner's] case because his theory of causation relies on an autoimmune disease causing neuroinflammation." *Id.* at 12 (quoting Decision Den. Compensation at 4). "Accordingly," respondent argues, "it was necessary and legally correct for the Special Master to undertake a preliminary inquiry regarding whether petitioner met his burden in proving that Ms. Mager suffered from autoimmune epilepsy." *Id.*

Respondent argues petitioner now disavows his allegation that Ms. Mager's seizure was caused by her autoimmune epilepsy. Resp. to Mot. for Review at 12. According to respondent, "[i]f petitioner was not relying on a diagnosis of autoimmune epilepsy, or wanted the Special Master to consider criteria from a different condition, he had plenty of chances to clarify his position. As the Special Master points out, '[t]he parties have had ample opportunity to develop their positions through submissions of evidence (primarily medical records) about [Ms. Mager], lengthy and multiple expert reports, and thorough briefing.'" *Id.* at 12 (quoting Decision Den. Compensation at 18).

Regarding the Special Master's decision to resolve the claim without an evidentiary hearing, respondent argues "[t]he Vaccine Rules explicitly authorize a special master to make findings of fact and decide a case on the basis of the written record without an evidentiary hearing." *Id.* at 14 (citing VRCFC 8(d); *Dickerson v. Sec'y of Dep't of Health & Hum. Servs.*, 35 Fed. Cl. 593, 598 (1996); *Plummer v. Sec'y of Dep't of Health & Hum. Servs.*, 24 Cl. Ct. 304, 307 (1991)). Respondent cites 42 U.S.C. § 300aa-12(d)(3)B(v) (2018), which provides a special master "*may* conduct such hearings as may be reasonable and necessary," (emphasis added), for supporting its argument the decision whether to hold a hearing is within the Special Master's discretion. *Id.*

According to respondent, the Special Master afforded petitioner a full and fair hearing:

> It is evident from the case record that the Special Master carefully evaluated all of the evidence and decided the case on the merits. The Special Master found that petitioner's "claim fails for reasons that a hearing could not cure given the paucity of evidence establishing a diagnosis of autoimmune epilepsy, which is essential for the remainder of [petitioner's] claim to proceed." The Special Master observed, "[petitioner] has had a full and fair opportunity to present his case. Thus, a disposition on the papers is appropriate."

Id. at 15 (quoting Decision Den. Compensation at 18). Respondent further argues the Special Master's decision to forgo an evidentiary hearing conserved judicial resources and provided a simplified process consistent with the legislative intent of the Vaccine Act. *Id.*

IV. Legal standards

A. The Court's Standard of Review of a Special Master's Decision

The Vaccine Act provides this Court jurisdiction to review a Special Master's decision upon timely motion of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing the record of the proceedings before the Special Master, the Court may: (1) "uphold the findings of fact

and conclusions of law of the special master and sustain the special master's decision"; (2) "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law"; or (3) "remand the petition to the special master for further action in accordance with the court's direction." § 300aa-12(e)(2). "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Saunders v. Sec'y of Dep't of Health & Hum. Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting *Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

It is not the Court's role "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871). The Court also does "not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." *Id.* (quoting *Munn*, 970 F.2d at 871). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009). The arbitrary and capricious standard "is a highly deferential standard of review[:] [i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

B. The Standard of Causation in Vaccine Cases

"A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1341 (Fed. Cir. 2010) (citing 42 U.S.C. §§ 300aa-11(c)(1), 13(a)(1) (2018)). "A petitioner can show causation under the Vaccine Act in one of two ways": (1) "by showing that she sustained an injury in association with a vaccine listed in the Vaccine Injury Table[,] . . . [i]n such a case, causation is presumed"; or (2) "if the complained-of injury is not listed in the Vaccine Injury Table . . . the petitioner may seek compensation by proving causation in fact." *Id.* at 1341–42 (internal citations omitted). Vaccine cases employ a burden shifting standard: "[o]nce the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine." *Id.* at 1342 (citing *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010); 42 U.S.C. § 300aa-13(a)(1)(B)).

"When a petitioner has suffered an off-Table injury . . . [the Federal Circuit] has established the following test for showing causation in fact under the Vaccine Act:"

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing

> that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Broekelschen, 618 F.3d at 1345 (quoting *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Under the first prong of *Althen*, "[a] petitioner must provide a 'reputable medical or scientific explanation' for its theory." *Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, [the explanation] must still be 'sound and reliable.'" *Id.* (quoting *Knudsen ex rel. Knudsen v. Sec'y of Dep't of Health & Hum. Servs*., 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Petitioners "need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act." *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs*., 569 F.3d 1367, 1379 (Fed. Cir. 2009). Where such evidence is introduced, it must not be viewed "through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard . . . ." *Id.* at 1380. For satisfying the second *Althen* prong, "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Health & Hum. Servs*., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280). Lastly, "the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008).

C. The Standard for Issuing a Decision on the Papers Without a Hearing in Vaccine Cases

The Court may "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 42 U.S.C. § 300aa-12(e)(2)(B). This is a "highly deferential standard of review." *Burns ex. rel. Burns v. Sec'y of Dep't of Health & Hum. Servs.*, 3 F.3d 415, 416 (Fed. Cir. 1993) (quoting *Hines ex. rel. Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). The Special Master's discretionary rulings are reviewed for abuse of discretion; such rulings "rarely come into play except where the special master excludes evidence." *Dickerson v. Sec'y of Dep't of Health & Hum. Servs.*, 35 Fed. Cl. 593, 597 (1996) (citing *Munn*, 970 F.2d at 870 n.10).

The Vaccine Act provides "a special master *may* conduct such hearings as may be reasonable and necessary." 42 U.S.C. § 300aa-12(d)(3)(B)(v) (emphasis added). A "special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." VRCFC 8(d); *Plummer*, 24 Cl. Ct. 304.

This Court has held that a special master's discretion to hold an evidentiary hearing is tempered by the requirement that:

> The special master shall be responsible for conducting all proceedings, including requiring such evidence as may be appropriate, in order to prepare a decision, including findings of fact and conclusions of law . . . [and] shall determine the nature of the proceedings, with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case . . . .

Dickerson, 35 Fed. Cl. at 598 (citing VRCFC 3(b)). Accordingly, "it is incumbent upon [a special master] to explain to the parties the evidence which is necessary and provide them a reasonable opportunity to come forward with it." *Id.*

V. Review of the Special Master's Decision

A. The Special Master's Consideration of Mr. Mager's Proposed Causation Theory

Mr. Mager argues the Special Master mischaracterized his argument on causation and ignored significant points made by petitioner's expert. Mot. for Review at 2, ECF No. 191. Petitioner acknowledges his expert believed Ms. Mager's epilepsy was autoimmune in nature, but he contends "his argument for causation does not *hinge* [on] a diagnosis of autoimmune epilepsy base[d] on the diagnostic criteria presented to the Court." *Id.* at 16. "In fact," petitioner argues, "the Special Master's reliance on that diagnostic criteria referenced in his opinion, directly contradicts [p]etitioner's stated reason for offering the criteria." *Id.* According to petitioner, he provided the diagnostic criteria "*solely* to demonstrate that autoimmune epilepsy can present as milder epilepsy." *Id.* at 16–17 (quoting Pl.'s Resp. to Special Master's 16 June 2021 Questions at 1, ECF No. 188). Petitioner clarifies:

> In other words, [p]etitioner is not hinging his case on a diagnosis of autoimmune epilepsy, *nor* did he proffer the diagnostic criteria to support a diagnosis of autoimmune epilepsy. Rather, [p]etitioner argued that [Ms. Mager] experienced SUDEP as a result of her epilepsy which was, yes, likely to be autoimmune in nature.

Id. Petitioner argues further the Special Master failed to address his "predominant argument," which he summarizes as follows:

> [Ms. Mager] experienced challenge/rechallenge, i.e.[,] that [Ms. Mager]'s presentation meets the classic definition of challeng[e]/rechallenge, i.e.[,] "*rechallenge*, an adverse event that occurred after more than one administration of a particular vaccine in the same individual." Rechallenge is *not* dependent on a finding that [Ms. Mager] suffered from autoimmune epilepsy. It is dependent on [Ms. Mager] suffering an adverse event, in this case seizures, after more than one administration of a particular vaccine, e.g.[,] the HPV vaccination.

Id. "[T]he complexity of [Ms. Mager's] diagnosis," petitioner contends, "cannot be stripped down to the three criteria as the Special Master did in this case. *Particularly*, when that criteria is offered to demonstrate that autoimmune epilepsy can present in a range of severity including the milder epilepsy from which [Ms. Mager] suffered." Mot. for Review at 16–17. Petitioner

concludes the Special Master abused his discretion by allegedly failing to consider the entirety of petitioner's case. *Id.* at 2, 16, 18.

The government contended at oral argument the Special Master's characterization of petitioner's argument is a factual determination subject to review under the arbitrary and capricious standard. Tr. at 23:10–25:6. At the same time, the government recognized it is an exercise of discretion for a special master to exclude evidence or impose limitations on the record, and such decisions are subject to review for abuse of discretion. Tr. at 26:24–27:22 ("[GOVERNMENT]: . . . [Decisions to admit or exclude evidence] are prime examples of exercise of judicial discretion. Limitation of the record, I construe in similar terms, in terms of making decisions about what the Court will or will not consider . . . . And those are things that are within the Special Master's discretion and, therefore, there may be instances where that discretion might be abused."). The government also recognized it "would not necessarily be solely a factual error" for a special master to rely on a flawed characterization of petitioner's case but struggled to identify the proper standard of review for such a scenario. Tr. at 30:19–31:9.

The Court disagrees with the government's argument that a special master's characterization of a petitioner's theory of causation is a factual determination. The Federal Circuit has held a special master's rulings are subject to review for abuse of discretion if they exclude evidence or limit the record on which the special master relies. *Contreras v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1363, 1368 (Fed. Cir. 2017); *Lampe v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 632, 636 (1998) (citing *Saunders*, 25 F.3d at 1033). In *Contreras*, the Federal Circuit found a special master abused his discretion by limiting his analysis to a single diagnosis even though the petitioner alleged two diagnoses and the government did not dispute the nature of the petitioner's injury. *Contreras*, 844 F.3d at 1368. According to the Federal Circuit, the special master's decision to limit his analysis to a single diagnosis improperly limited the record such that the special master did not consider evidence relevant to the spurned diagnosis. *Id.* at 1368–69. Thus, a special master's characterization of a petitioner's theory of causation is subject to review for abuse of discretion. *Id.* at 1368 ("We review discretionary rulings—i.e., exclusion of evidence or limitation of the record upon which the special master relies—under the abuse of discretion standard.") (citing *Munn*, 970 F.2d at 870 n.10).

The Court may set aside a special master's decision for abuse of discretion "if the decision is clearly unreasonable, arbitrary, or fanciful; is based on an erroneous conclusion of law; rests on clearly erroneous fact findings; or involves a record that contains no evidence on which the [special master] could base its decision." *Cottingham ex. rel. K.C. v. Sec'y of Health & Hum. Servs.*, 971 F.3d 1337, 1345 (Fed. Cir. 2020) (citing *In re Durance*, 891 F.3d 991, 1000 (Fed. Cir. 2018)).

Petitioner's prehearing brief summarized his argument on causation as follows:

> Petitioner's theory of causation is a neurological autoimmune process triggered by the HPV vaccine, causing *autoimmune epilepsy*, which is strongly supported by the challenge/rechallenge, . . . i.e.[,] "*rechallenge*, an adverse event that occurred after more than one administration of a particular vaccine in the same individual." [Ms. Mager] experienced a similar adverse event after each of two administrations

> of her HPV vaccination. Further [Ms. Mager's] HPV vaccination triggered an immune-mediated response that resulted in the development of her *autoimmune epilepsy* after her first dose, and subsequently caused the significant aggravation of her *autoimmune epilepsy* (characterized by recurrence of seizures, increased frequency of seizures and death from SUDEP). As it is medically most likely, the seizures she suffered after the first and the second HPV vaccination represent the same medical condition.

Pet'r's Prehr'g Br. at 16–17, ECF No. 168 (emphasis added). Notably, petitioner's prehearing arguments mention three times that the HPV vaccine resulted in autoimmune epilepsy. Petitioner agrees Ms. Mager's condition does not satisfy the diagnostic criteria for autoimmune epilepsy, Tr. at 34:7–20, but he argues Ms. Mager's condition was a milder form of generalized epilepsy that was autoimmune in nature and caused by an autoimmune reaction. Tr. at 52:14–53:2. In other words, petitioner argues Ms. Mager's condition is not Autoimmune Epilepsy—"capital *A*, capital *E*"—as defined by the diagnostic criteria but epilepsy that is autoimmune in nature. Tr. at 108:15–109:9. The parties agreed arguendo considering petitioner's distinction this way—i.e., *Autoimmune Epilepsy* being defined by the diagnostic criteria and *autoimmune epilepsy* being epilepsy that is autoimmune in nature—assists with discussion. Tr. at 108:19–110:8 ("THE COURT: . . . If there is a distinction between Autoimmune Epilepsy, capital A, capital E [,] . . . and just autoimmune epilepsy, lowercase—[GOVERNMENT]: Got it.").

To support his argument, petitioner pointed to "the direct relationship with the HPV vaccination strongly supported by the challenge/rechallenge circumstances." Pet'r's Prehr'g Br. at 9. He also referred to "[a]dditional supporting evidence" of inflammation of the brain, which was detailed in the postmortem report. *Id.*

Petitioner further argued the medical literature demonstrates autoimmune epilepsy can be difficult to distinguish from other types of epilepsy. For example, petitioner referred to an Australian study involving 114 patients with new onset seizures, 11 of which tested positive for one or more autoantibodies compared to three of 65 control patients. *Id.* at 39–40 (citing Pet'r's Ex. 88, ECF No. 165-5). Petitioner summarized disparate data characterizing patients with and without autoantibodies and suggested this data demonstrates autoimmune epilepsy presents in various ways and can be difficult to identify. *Id.* at 40. Petitioner explained:

> Overall, there was no significant difference in the demographic or clinical pictures between the antibody positive and the antibody negative group. . . . The article does not prove that the antibodies were the cause of the epilepsy, but it is a very solid possibility . . . . Overall, [the article] shows that neuronal antibodies are relatively common in patients with new onset epilepsy, which is otherwise considered idiopathic and that the epileptic presentation is very variable.

Id. at 40–41. In other words, autoimmune epilepsy can be difficult to distinguish from other types of epilepsies.[4] This study, petitioner argued, also demonstrates autoimmune epilepsy can

[4] While petitioner speaks of neuronal antibodies as an indicator of autoimmune epilepsy, Ms. Mager's blood was never tested for neuronal antibodies. The Special Master recognized petitioner's "potentially valid reasons" why

present in milder epilepsy cases. *Id.* at 9–10. Petitioner referred to this study, along with the diagnostic criteria for autoimmune epilepsy, to support the proposition that autoimmune epilepsy can present as milder epilepsy. Pet'r's Prehr'g Br. at 9–10. Petitioner held this position consistently throughout the prehearing proceedings.[5]

Before making his decision on compensation, the Special Master followed up with petitioner asking him to "identify the source of the diagnostic criteria for autoimmune epilepsy listed in his [prehearing] brief." Order at 1, ECF No. 187. Petitioner responded accordingly but noted "[t]he criteria are discussed in that section solely to demonstrate that autoimmune epilepsy can present as milder epilepsy." Pl.'s Resp. to Special Master's 16 June 2021 Questions at 1.

In his decision denying compensation, the Special Master acknowledged and quoted petitioner's language identifying the source of his diagnostic criteria, Decision Den. Compensation at 4 n.3, ECF No. 189, but omitted petitioner's clarification that "[t]he criteria are discussed *solely* to demonstrate that autoimmune epilepsy can present as milder epilepsy," Pl.'s Resp. to Special Master's 16 June 2021 Questions at 1 (emphasis added). The Special Master then proceeded to apply the diagnostic criteria to the evidence in the record despite petitioner's clarification, ultimately concluding there was insufficient evidence to support a diagnosis of Autoimmune Epilepsy and denying petitioner's claim on that basis. *Id.* at 16–17.

The exchange between the Special Master and petitioner clarifying the source and purpose of the diagnostic criteria demonstrates two important points: (1) petitioner was not arguing a diagnosis of Autoimmune Epilepsy was necessary; and (2) there was a misunderstanding between petitioner and the Special Master concerning the relevance of the diagnostic criteria for autoimmune epilepsy. Counsel for the government—who also acknowledges misunderstanding the argument—recognizes the Special Master may have misunderstood petitioner's argument. Tr. at 61:22–25 ("COURT: So is it possible the Special Master misunderstood [p]etitioner's argument? [GOVERNMENT]: I certainly did, so certainly that's possible."). Petitioner's clarification apparently did not clear up that misunderstanding since the Special Master proceeded to apply the diagnostic criteria as if it were central to his argument.[6] *See* Decision Den. Compensation.

While the Special Master's analysis of the diagnostic criteria was careful and thorough, it was also not necessary—petitioner agrees Ms. Mager's condition does not fit the diagnostic criteria neatly. Tr. at 34:7–20 ("I do not believe that she meets the diagnostic criteria. Neither does Dr. Shafrir . . . . We've not alleged that she meets that diagnostic criteria in this case."). Petitioner argues the diagnostic criteria are a starting point but there is no requirement that they be firmly adhered to. Tr. at 37:12–38:3 ("The diagnostic criteria . . . [are] the point where you

---

Ms. Mager's doctors did not test her blood for neuronal antibodies, such as the emerging nature of the diagnosis. Decision Den. Compensation at 10.

[5] As discussed below, petitioner maintained this position when asked to identify the source of his diagnostic criteria. He responded: "[t]he criteria are discussed in that section solely to demonstrate that autoimmune epilepsy can present as milder epilepsy." Pl.'s Resp. to Special Master's 16 June 2021 Questions at 1, ECF No. 188.

[6] The Special Master's apparent misunderstanding of petitioner's argument likely could have been clarified if a hearing had been held.

start. . . . And the diagnostic criteria [are] typically based on developing treatment modalities and things like that. In a clinical setting, doctors use diagnostic criteria, but they're not married to them. . . . [Y]ou get people diagnosed all the time [who] don't meet diagnostic criteria.").

The Vaccine Act jettisons strict adherence to diagnostic criteria for a more flexible approach to proving causality. *Knudsen ex rel. Knudsen v. Sec'y of Dep't of Health & Hum. Servs*., 35 F.3d 543, 548–49 (Fed. Cir. 1994) ("Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain.") (citing *Bunting v. Sec'y of Dep't of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991)); *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) ("[T]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury.'" (quoting *Knudsen*, 35 F.3d at 549)).

In providing a thorough analysis of the diagnostic criteria, the Special Master missed the core of petitioner's argument—the vaccine caused an autoimmune response triggering recurrence and aggravation of Ms. Mager's epilepsy disorder. Tr. at 63:10–14. Petitioner devoted several pages of arguments in support of his theory that the HPV vaccine triggered recurrence and aggravation of Ms. Mager's seizure disorder, *see* Pet'r's Prehr'g Br. at 14–17; these arguments were unaddressed in the Special Master's decision, Tr. 75:10–76:2 ("COURT: So explain that out more. That there was not proper weight given to challenge/rechallenge. [PETITIONER]: . . . I don't think [the Special Master] did any analysis [in] that regard. . . . COURT: Does the [g]overnment have anything on that? [GOVERNMENT]: I don't believe he did.").

By focusing his analysis on the diagnostic criteria for Autoimmune Epilepsy—criteria the petitioner provided only to demonstrate the breadth of severity with which autoimmune epilepsy can manifest—the Special Master did not consider petitioner's primary argument; i.e., an autoimmune reaction to the HPV vaccine triggered recurrence and aggravation of Ms. Mager's epilepsy disorder. The Special Master is statutorily mandated to consider all relevant medical and scientific evidence contained in the record, 42 U.S.C. § 300aa-13(b)(1); the Court therefore must find this constitutes an abuse of discretion, *Contreras*, 844 F.3d at 1368–69 (finding a special master committed reversible error by failing to consider relevant evidence related to the petitioner's medical theories).

B. The Special Master's Legal Requirement, if any, to Analyze the Case Under *Althen* and its Progeny

The parties in this case agree Ms. Mager suffered from an epileptic seizure disorder, but they dispute the underlying diagnosis of the disorder—petitioner argues autoimmune epilepsy while the government argues JME. Decision Den. Compensation at 4. In view of these competing diagnoses, the Special Master, citing *Lombardi* and *Broekelschen*, set out as a threshold matter to determine which diagnosis was correct. The Special Master found petitioner did not meet his burden to show by preponderant evidence Ms. Mager suffered from

Autoimmune Epilepsy. *Id.* at 16–17. The Special Master considered a diagnosis of Autoimmune Epilepsy to be necessary for petitioner to succeed, so he denied the petition without analyzing whether the vaccine caused or aggravated Ms. Mager's epilepsy disorder under *Althen*. *Id.* The Court reviews de novo the Special Master's decision to diagnose Ms. Mager's condition and dismiss the case without analyzing whether the HPV vaccine caused Ms. Mager's injury under *Althen*. *Broekelschen*, 618 F.3d at 1345 (holding the Court "owe[s] no deference to the . . . special master on questions of law.").

For off-Table vaccine cases, the petitioner bears the burden of showing she "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table . . . ." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). "[T]he statute places the burden on the petitioner to make a showing of at least one defined and recognized injury . . . not merely a symptom or manifestation of an unknown injury." *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act provides compensation for "*any* illness, disability, injury, or condition *not set forth in the Vaccine Injury Table* . . . which was caused by a [designated] vaccine . . . ." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (emphasis added). A petitioner need not diagnose her injury, she must merely "show that the vaccine in question caused [her] injury—regardless of the ultimate diagnosis." *Kelley v. Sec'y of Health & Hum. Servs.*, 68 Fed. Cl. 84, 100 (2005) (citing 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I)). If, however, "the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." *Lombardi*, 656 F.3d at 1352 (citing *Broekelschen*, 618 F.3d at 1346). Absent a "showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." *Lombardi*, 656 F.3d at 1353.

In this case, petitioner alleges the HPV vaccine caused or aggravated Ms. Mager's epileptic seizure disorder ultimately resulting in her death. Am. Pet. at 2, ECF No. 11; Mot. for Review at 10. Petitioner submitted evidence showing Ms. Mager indeed suffered from an epileptic seizure disorder that caused her death. The government does not dispute this. Tr. at 95:8–11. Instead, the government contends Ms. Mager's injury could not have been caused by the vaccine because her underlying diagnosis is better diagnosed as JME. The government's argument fails, however, because JME and autoimmune epilepsy are variants of the same disorder—i.e., a seizure disorder. Gov't's Prehr'g Br. at 14, ECF No. 180 (arguing Ms. Mager suffered from a generalized seizure disorder); Gov't's Ex. BB at 12, ECF No. 183-1 (explaining Ms. Mager was diagnosed with a primary generalized epilepsy disorder); Tr. at 95:8–11 ("COURT: . . . The Government does not disagree that [Ms. Mager] suffered from a seizure disorder. [GOVERNMENT]: No."); Tr. at 93:12–15 ("[PETITIONER]: I mean, they're both epilepsy and they're both seizure disorders.").

While this case involves competing diagnoses, they are only *competing* in the sense that the parties dispute them—not in the sense that they are mutually exclusive. Tr. at 85:23–25 ("[GOVERNMENT]: Do I think there's anything that would preclude her from having an autoimmune response, no."). While autoimmune epilepsy is characterized in terms of its etiology, or causality, Tr. at 7:14–20, 40:19–22, JME is characterized in terms of its phenotype, or observable characteristics, *see* Gov't's Ex. BB at 2. Unlike the competing diagnoses in

Broekelschen and *Lombardi*, juvenile myoclonic epilepsy is an idiopathic generalized epilepsy disorder—its cause is unknown. Gov't's Ex. BB at 2. The question of causation cannot turn on a diagnosis if its underlying cause is unknown, particularly when the disputed diagnoses are variants of the same disorder as they are here. *Broekelschen*, 618 F.3d at 1346, 1349 (holding where "the injury itself is in dispute, the proposed injuries differ significantly in their pathology, *and the question of causation turns on* [*the*] *injury*" it is appropriate for the special master to first determine which injury the evidence supports).

The outcome in *Lombardi* is also distinguishable from the outcome in this case because *Lombardi* was "unusual in that the identification of the injury and its nature [were] in dispute." *Lombardi*, 656 F.3d at 1352. In contrast, there is no dispute in this case that Ms. Mager suffered from an epileptic seizure disorder that resulted in her death. Tr. at 95:8–11. Moreover, in addition to extreme disagreement between experts,[7] the Federal Circuit noted the competing conditions in *Lombardi* were not "so similar that doctors consider them to be conditions along a spectrum of diseases." *Lombardi*, 656 F.3d at 1352. By contrast, both competing diagnoses here are variants which fit within the category of epileptic seizure disorders. Tr. at 9:2–3; 12:4–5. Moreover, the government admits *Lombardi* is factually distinguishable from this case. Tr. at 91:5–8.

This case is distinguishable from *Broekelschen* for the same reasons, but also because the parties agree Ms. Mager suffered from a seizure disorder—a fact that distinguished *Broekelschen* from the Federal Circuit's precedents. *Broekelschen*, 618 F.3d at 1346 (distinguishing *Broekelschen* from *Andreu* because "the parties agreed that the petitioner suffered from a seizure disorder"). Further, the competing diagnoses in *Broekelschen* are unlike the two competing diagnoses in this case, which are both epileptic in nature and variants of the same disorder. *Cf. Broekelschen*, 618 F.3d at 1346.

The Special Master's inquiry into the underlying diagnosis of Ms. Mager's seizure disorder places too much emphasis on the diagnostic criteria for autoimmune epilepsy and too little on whether she suffered an injury. *See*, *e.g.*, Decision Den. Compensation at 4 ("The difference between autoimmune epilepsy and JME affects the outcome of [petitioner's] case because his theory of causation relies on an autoimmune disease causing neuroinflammation."). The inquiry improperly narrows the analysis on diagnostic criteria the petitioner never alleged it satisfied. By narrowly focusing on the diagnostic criteria, the Special Master denied the petitioner's claims on grounds the petitioner never argued in making his case. Tr. 29:9–30:9 ("And in doing that, it essentially set up a strawman argument that could be knocked down. You know, we can't defend a diagnosis that we didn't allege."). In doing so, the Special Master effectively abbreviated the causation analysis, which is an improper application of the Federal Circuit's holding in *Broekelschen*. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357

[7] The petitioner in *Lombardi* alleged she suffered from three different medical conditions: transverse myelitis, chronic fatigue syndrome, and systemic lupus erythematosus. *Lombardi*, 656 F.3d at 1351. The government's experts, on the other hand, refuted the petitioner's proposed medical conditions and proposed five others. *Id.* at 1352–53. Further complicating matters, the government's expert witness testimony "refuted each of those diagnoses and proposed five other possible conditions that Lombardi may have suffered from." *Id*. "In the face of such extreme disagreement among well-qualified medical experts," the Federal Circuit reasoned, "it was appropriate for the special master to first determine what injury, if any, was supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Id*. at 1352–53.

(Fed. Cir. 2013) (explaining where parties agreed on injury and "the issue [was] whether the vaccine caused [p]etitioner's [injury], the special master should have expressly applied the analysis set forth in *Althen*"); *Lombardi*, 656 F.3d at 1358 (O'Malley, J., concurring) (expressing concern with "provid[ing] a mechanism for special masters to shortcut the causation analysis in instances where the alleged injuries can support multiple diagnoses"); *see also Broekelschen*, 618 F.3d at 1352 (Mayer, J., dissenting on other grounds) ("[The] approach, of first assigning a diagnosis to [petitioner's] symptoms before applying the *Althen* test, is not supported by statute, caselaw, or logic, and its effect [is] to impermissibly heighten [petitioner's] burden.").

The "existence and nature of the injury" was not in dispute, so the Special Master erred in failing to consider whether the vaccine caused Ms. Mager's injury under *Althen* and its progeny. *W.C.*, 704 F.3d at 1357 (finding the special master improperly failed to carry out analysis under *Althen* where parties agreed on petitioner's injury); *Contreras*, 844 F.3d at 1368–69 (finding the special master erred by inquiring into petitioner's diagnosis and failing to conduct a complete *Althen* analysis for all medical disorders alleged by the petitioner). For these reasons, the Court finds the Special Master must perform the requisite causation analysis under *Althen* and its progeny. *W.C.*, 704 F.3d at 1357 (finding where parties agreed on injury and "the issue [was] whether the vaccine caused [p]etitioner's [injury], the special master should have expressly applied the analysis set forth in *Althen*"); *Contreras*, 844 F.3d at 1368 (finding the special master erred in conducting a threshold inquiry into the specific diagnosis of the alleged vaccine injury).

VI. Whether the Special Master is Obliged to Consider the Entire Record in View of his Decision to not Hold an Evidentiary Hearing

In deciding the case on the papers without an evidentiary hearing, the Special Master reasoned "[a] hearing to determine the threshold issue of diagnosis in this case is not needed. The parties have had ample opportunity to develop their positions through submissions of evidence (primarily medical records) about [Ms. Mager], lengthy and multiple expert reports, and thorough briefing." Decision Den. Compensation at 18. Petitioner argues, under *Moriarty*, the Special Master's decision to forgo an evidentiary hearing in this case requires the Special Master to consider the entire record. Mot. for Review at 15–16. Petitioner acknowledges the Special Master is not *required* to conduct an evidentiary hearing but contends "[i]f a [s]pecial [m]aster may not, as a matter of law, decline to consider evidence on the record only because it was not discussed at [a] hearing it is even more imperative that he consider all the evidence when he also declines to *conduct* a hearing." *Id.* The Court reviews discretionary rulings, such as exclusion of evidence or limitation of the record, upon which the Special Master relies under the abuse of discretion standard. *Contreras*, 844 F.3d at 1368.

The Vaccine Rules authorize a special master to make findings of fact and decide a case based on the written record without an evidentiary hearing. *See* VRCFC 8(d); *Plummer v. Sec'y of Dep't of Health & Hum. Servs.*, 24 Cl. Ct. 304, 307 (1991). Whether to hold a hearing is a matter within a special master's discretion. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (a special master "*may* conduct such hearings as may be reasonable and necessary") (emphasis added). The Vaccine Act requires a special master to consider any medical records or reports "contained in the record regarding the nature, causation, and aggravation of the petitioner's . . . injury" as well as "all other relevant medical and scientific evidence contained in the record." 42 U.S.C.

§ 300aa-13(b). The statute also requires special masters to "'consider the entire record and the course of the injury' when evaluating the weight to be afforded to any medical records or reports present in the record." *Moriarty by Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1327 (Fed. Cir. 2016) (quoting 42 U.S.C. § 300aa-13(b)). Accordingly, a special master must consider any *relevant* medical records or reports contained in the entire record of the case. *Id.* Unless the Special Master expressly indicates he did not consider certain evidence, a presumption applies that he "considered the relevant record evidence even though he does not explicitly reference such evidence in his decision." *Id.* at 1328.

The inquiry in this case is straightforward. The Court starts from the presumption that "a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision." *Id.* In this case, the Special Master did not expressly indicate he did not consider certain relevant evidence. *See* Decision Den. Compensation. Petitioner admits there is no indication in this case the Special Master failed to consider evidence relevant to a diagnosis of autoimmune epilepsy. Tr. at 35:10–23. In the absence of any indication the Special Master failed to consider any relevant evidence for a diagnosis of autoimmune epilepsy, the presumption maintains.

Petitioner is correct that a special master is required to consider the entire record of the case, 42 U.S.C. § 300aa-13(b), but petitioner has not shown that the Special Master failed to consider any relevant evidence. Moreover, petitioner neglects the Federal Circuit's emphasis on *relevant* evidence, *Moriarty*, 844 F.3d at 1327–28 ("[A] special master . . . must consider all *relevant* medical and scientific evidence . . . , which includes any *relevant* medical records or reports. . . . [T]he special master 'shall' consider the entire record, which includes this relevant evidence . . . ."). A special master's burden to consider evidence contained within the record extends only to evidence relevant to the factual inquiry at hand. *Moriarty*, 844 F.3d at 1327–28; 42 U.S.C. § 300aa-13(b). The Federal Circuit in *Moriarty* found the special master in that case erred by failing to consider relevant expert testimony. *Moriarty*, 844 F.3d at 1328. There is no indication here that the Special Master did not consider evidence relevant to Ms. Mager's diagnosis.

To the extent the Special Master was required to consider all evidence relevant to making a factual finding on Ms. Mager's diagnosis, the Court finds the Special Master did not err. *Id.* As discussed above, however, the Special Master improperly viewed the evidence through the narrow lens of diagnostic criteria rather than petitioner's actual theory and failed to carry out a causation analysis under *Althen* and its progeny. The Court makes no finding regarding whether the Special Master considered all relevant evidence to that inquiry.

VII. Conclusion

For the above reasons, petitioner's motion for review is **GRANTED** and the Special Master's 29 July 2021 Decision Denying Compensation, ECF No. 189, is **VACATED**. The case is **REMANDED** for the Special Master to determine whether petitioner can satisfy the required

elements for an off-Table claim under *Althen* and its progeny, and for other proceedings consistent with this Opinion.

IT IS SO ORDERED.

s/ Ryan T. Holte
RYAN T. HOLTE
Judge